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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/785,532	01/17/1997	JOE W. GRAY	2500.124US2	4124

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EXAMINER	
DAVIS, MINH TAM B	
ART UNIT	**PAPER NUMBER**
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	08/785,532	GRAY ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-28,37 and 61-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-28,37 and 61-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/24/97; 11/25/02; 11/14/03; 03/02/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 26-28, 37, 61-63, SEQ ID NO:9 are examined in the instant application.

The following are the remaining rejections.

Specification

The specification remains objected to because it contains empty space, for example on page 2, line 17.

NEW REJECTION BASED ON THE AMENDMENT

Objection

Claims 26-28, 37, 61-63 are objected to, because it is not clear in claim 26 an increase in the copy number of ZABC1 (SEQ ID NO:9) is an increase as compared to what.

Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-28, 37, 61-63 of the instant application are non-provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,808,878 B1, in view of Tanner et al, 1994, Cancer Res, 54: 4257-4260, of record.

The following are claims 26-28, 37, 61-63 of the instant application.

Claim 26 is drawn to: A method of detecting in a sample the presence of metastatic breast cancer, the method comprising:

contacting a nucleic acid sample from breast tissue cells of a human patient with a probe which specifically hybridizes under stringent conditions to a target polynucleotide sequence consisting of the sequence of SEQ ID NO:9, or the complete complement thereof, wherein said stringent conditions include washing with 0.2x SSC at 65°C for 15 minutes, wherein the probe is contacted with the sample under conditions in which the probe hybridizes selectively with the target polynucleotide sequence to form a stable hybridization complex; and

detecting the formation of the hybridization complex, and the increase in the copy number of ZABC1 (SEQ ID NO:9), and correlating the increase in the copy number of ZABC1 (SEQ ID NO:9) with the presence of metastatic breast cancer.

Claim 27 is drawn to: The method of claim 26, wherein the nucleic acid sample is from a patient with breast cancer.

Claim 28 is drawn to: The method of claim 26, wherein the nucleic acid sample is a metaphase spread or an interphase nucleus.

Claim 37 is drawn to: The method of claim 26, wherein the probe comprises a polynucleotide sequence as set forth in SEQ ID NO:9.

Claim 61 is drawn to: The method of claim 26, wherein the probe is labeled. Claim 62 is drawn to: The method of claim 61, wherein the label is a fluorescent label.

Claim 63 is drawn to: The method of claim 26, wherein the nucleic acid sample is a chromosome.

The following are claims 1-3 of U.S. Patent No. 6,808,878 B1.

Claim 1 is drawn to: A method for screening for neoplastic cells in a sample, the method comprising: contacting a nucleic acid sample from a human patient with a probe consisting

essentially of SEQ ID NO:9, wherein the probe is contacted with the sample to form a stable hybridization complex; detecting the formation of said hybridization complex, wherein an increase in the level of the hybridization complex relative to the level of a hybridization complex formed from a nucleic acid sample from non-neoplastic human cells is indicative of amplification of the sequence to which SEQ NO:9 has hybridized, and that said cells from a human patient are neoplastic cells.

Claim 2 is drawn to: The method of claim 1, wherein the nucleic acid sample is from a patient with breast cancer.

Claim 3 is drawn to: The method of claim 1, wherein the nucleic acid sample is a metaphase spread or an interphase nucleus.

Claims 1-3 of U.S. Patent No. 6,808,878 B1 do not teach a method for detecting metastatic breast cancer. Claims 1-3 of U.S. Patent No. 6,808,878 B1 do not teach that the probe is labeled, wherein the label could be fluorescent. Claims 1-3 of U.S. Patent No. 6,808,878 B1 do not teach that the nucleic acid sample is a chromosome.

Tanner et al, 1994 teach detecting **invasive breast carcinoma**, using the probe RMC20C001 of 1.5 Mb, to detect breast cancer (abstract, p.4257, second column, last paragraph), which probe inherently encompasses SEQ ID NO:9 of 10 kb, in view of the disclosure in the instant specification that SEQ ID NO:9 lies within the amplified 20q13 region complementary to RMC20C001 (figure 5 of the instant specification). Tanner et al teach that three to six-fold increase in relative gene copy number at RMC20C001 is found in breast carcinoma (p.4259, first column, item under "Analysis of Primary Breast Cancers"). Tanner et al teach that the biotin-labeled probe is detected with avidin-fluorescein isothiocyanate for use

under fluorescence microscope and interphase scoring (p.4259, first column, first two paragraphs). Tanner et al teach that metaphase chromosomes of normal blood lymphocyte is used as control in pair-wise two color FISH (p. 4257, second column, last three lines of paragraph before last, p.4259, first column, last three lines of second paragraph).

One would have expected that the method of U.S. Patent No. 6,808,878 B1 would detect metastatic breast cancer, because an increase in copy number of genes in the region detected by RMC20C001 is found in invasive breast carcinoma, as taught by Tanner et al, which RMC20C001 probe inherently encompasses SEQ ID NO:9 of 10 kb.

Further, it would have been obvious to label the probe taught by U.S. Patent No. 6,808,878 B1 with a fluorescent label, using the method taught by Tanner et al, for conveniently detecting the presence of the probe under fluorescent microscope for in situ hybridization (FISH). It would have been obvious to use as a nucleic acid sample a chromosome, to make a metaphase spread, in view of the teaching U.S. Patent No. 6,808,878 B and Tanner et al.

Thus, although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept.

This is a non-provisional obviousness-type double patenting rejection because the conflicting claims have in fact been patented.

Conclusions

No claims are allowed.

The closest prior art is Tanner et al, supra. Although Tanner et al use the probe RMC20C001 of 1.5 Mb, to detect an invasive breast cancer, which probe encompasses SEQ ID

NO:9 of 10 kb, and would hybridize to SEQ ID NO:9, Tanner et al do not teach SEQ ID NO:9, and the specific method steps of: 1) detecting the formation of the hybridization complex between the probe and SEQ ID NO:9, 2) detecting the increase in the copy number of ZABC1 (SEQ ID NO:9), and 3) correlating the increase copy number of ZABC1 (SEQ ID NO:9) with the presence of a breast cancer cell that is likely to progress to metastasis. In other words, the claimed method provides an increased mapping precision as compared to the art, to a more defined, specific genomic sequence of about 10 kb, SEQ ID NO:9, as correlated with the presence of a metastatic breast cancer cell.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SHANON FOLEY can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS

January 29, 2007

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